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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,125	01/09/2001	Tadamitsu Kishimoto	053466/0296	6506

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
08/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/756,125	KISHIMOTO ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/21/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, remarks, terminal disclaimer, Sequence Listing, and IDS filed 7/14/10 have been entered. Applicant's IDS filed 6/21/10 has also been entered.

2. Claims 9, 13, and 14 are being acted upon.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. As set forth previously, Claims 9, 13, and 14 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 9, and 10 of U.S. Patent Application No. 11/585,172. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim and the claims of the '172 application both recite the a method of treating an IL-6 mediated disease, which would encompass chronic rheumatoid arthritis, by administering to a patient in need a PM-1 antibody, in particular the monoclonal hPM-1 antibody of FERM BP 2998 (which comprises the CDRs of the instant claims). Note that the method of inhibiting synovial cell growth of instant Claim 9 is clearly a treatment for arthritis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has submitted a terminal disclaimer that was disapproved on 8/02/10. Accordingly, the rejection has been maintained.

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 9, 13, and 14 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a rejection for the introduction of new matter into the claims.

As set forth previously, The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically: a method employing an antibody which is humanized using the CDR(s) of PM-1 (FERM BP-2998).

Applicant is advised that the claims are now drawn to a method employing a genus of antibodies, i.e., antibodies comprising PM-1 CDR(s) in any human antibody framework, that is not disclosed in the specification.

Applicant's arguments, filed 7/14/10, have been fully considered but are not found persuasive. Applicant argues that the specification supports the claimed subject matter at pages 6 and 10-11.

At page 6 the specification cites Hirata et al. (1989). This reference was addressed previously. It teaches a single PM-1 antibody and not the genus of antibodies employed in the method of the instant claims.

At page 11 the specification cites WO 92/19759, a translated copy of which was submitted to the Office on 2/03/05.

The specification merely refers to WO 92/19759 as teaching hPM-1, "a preferred example of a reshaped human antibody". The specification does not disclose the document as teaching a family of antibodies "humanized by using the complementary determination region of PM-1 deposited as FERM BP-2998 to replace the complementary determination region of a human antibody" as is claimed. Note that the specification refers to

PM-1 as an antibody, not a hybridoma. And it refers to WO 92/19759 for its teaching of an antibody, not a hybridoma. **FERM BP-2998 is a hybridoma; it is not an antibody.** Clearly, Applicant cannot pick a teaching out of WO 92/19759 that is not referred to in the instant specification. Additionally, a review of the document shows that it concerns only the "reshaping" of V_L and V_H regions, and then only by the substitution of an amino acid or two (see Tables 2 and 3). The document does not teach a whole the whole genus of complete antibodies encompassed for use in the method of the instant claims. For example, the document does not teach antibodies comprising a representative number of different framework regions nor does the document teach any constant regions at all.

Applicant argues that WO 92/19759 was not incorporated by reference and that said incorporation is not necessary.

Applicant is advised that if the document is considered to teach essential material incorporation by reference would not suffice in the instant application as incorporation by reference of essential material is limited to U.S. patents. Regardless, it is far too late in prosecution for such considerations now, nearly a decade, after the filing of the instant application.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from

7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla, can be reached on (571) 272-0878.

10. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

/G.R. Ewoldt/
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